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**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

| | |
|---|---|
| ALLERGAN SALES, LLC and ALLERGAN, INC.<br><br>Plaintiffs,<br><br>v.<br><br>SANDOZ, INC. and ALCON LABORATORIES, INC.<br><br>Defendants. | Civil Action No. 2:17-cv-10129-WHW-CLW<br><br>*Electronically Filed* |

**PLAINTIFFS ALLERGAN SALES, LLC'S AND ALLERGAN, INC.'S REPLY BRIEF IN SUPPORT OF THEIR MOTION FOR A PRELIMINARY INJUNCTION**

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## I. INTRODUCTION

Allergan's opening brief, and the supporting evidence that Allergan's declarants bring to this Court, show a preliminary injunction should issue. Allergan's expert ophthalmologist Dr. Robert Noecker laid out how the patented invention Combigan® was an important advancement in the treatment of a blinding disease. Dr. Noecker showed that Sandoz's generic formulation is an exact copy of Combigan® and covered by the claims, and explained how Sandoz will induce and contribute to infringement through sales of its product as labeled. That testimony stands unrebutted—Sandoz did not even offer testimony about the supposedly non-infringing "skinny label," thereby admitting (as another court already found) that it was nothing more than a gambit to avoid the injunction against its full-label product. Dr. Noecker also demonstrated how the claims—the limitations of which have been upheld as valid twice by district courts and twice by the Federal Circuit—are novel and nonobvious over the prior art. No Sandoz witness says otherwise. Additionally, Allergan's fact witness David LeCause and expert economist Dr. Robert Maness showed this Court how a generic launch would irreparably harm Allergan. Sandoz has not offered any economist to challenge them.

Allergan more than meets its burden, and Sandoz concedes that with its all or nothing throw of the dice on two issues: claim construction, and a far-fetched and legally improper unclean hands theory. As to the first, Sandoz argues for the first time after years of litigation that the "wherein" clauses related to the unexpected efficacy and adverse event benefits of Combigan® are not really claim limitations, despite spending the past nine years treating the very same types of clauses as limiting. Sandoz's claim construction argument ignores that the 2017 Federal Circuit opinion already found that the same efficacy and adverse event requirements ***are limiting*** because they "further restrict[] the method of administering the composition twice daily." And it also ignores the case law that Allergan cited in its claim construction briefs showing that Sandoz's repeated

refrain that "results" cannot add patentable weight is simply wrong where those "results" are material to the patentability of the claims. As to the second, Sandoz's unclean hands arguments are not only legally wrong and factually unsupported, but Sandoz does not appear to even believe them. If Sandoz could truly demonstrate that Allergan intentionally withheld material data showing that Combigan® is not superior to the prior art, it would have used that same data to show that the claims directed to equal efficacy and a better adverse event profile cannot be infringed. Sandoz also would argue directly here that Allergan cannot succeed on the merits at trial because of inequitable conduct, instead of relying on this shadow allegation of unclean hands. And most telling, it would have raised fraud long ago, because everything it now claims was an act of deception was known to Sandoz during the prior nine years of litigation over patents in the same family.

Because Sandoz has entirely failed to rebut Allergan's likelihood of success on the merits and failed to do anything to tip the balance of harms, which weighs heavily in Allergan's favor, Allergan respectfully requests that the Court grant its motion for a preliminary injunction.

## II. ARGUMENT

### A. Allergan Is Likely to Succeed on the Merits Because the "Wherein" Clauses Are Material Parts of the Claim and Are Limiting

The only substantive argument Sandoz makes to attempt to rebut Allergan's validity evidence is its new refrain that the "wherein" clauses of the asserted claims—on which the Federal Circuit based its validity finding for the prior patents and on which the Examiner based the allowance of the patents-in-suit—are meaningless words that add nothing to the claims. As set forth in detail in Allergan's claim construction briefs (Dkts. 57, 69), Sandoz's argument finds no support in the law and is belied by the Federal Circuit's opinions in the prior litigations, the file histories of the patents-in-suit, and Sandoz's own prior claim construction positions.

### B. Sandoz's Arguments that the "Wherein" Clauses Are Non-Limiting Conflict with the Prior Federal Circuit Opinions and Other Case Law

As an initial matter, Sandoz's argument that the "wherein" clauses are not limiting because they are "intended results" that "automatically follow from the composition itself" (Dkt. 115 at 21) is merely a repackaging of its failed inherency argument. The Federal Circuit has squarely rejected this argument, finding in its 2017 opinion that the same efficacy and adverse event limitations present in the claims here provide a further limitation beyond just administering a brimonidine/timolol fixed combination; in other words, they are not merely inherent expressions of intended result. In particular, the court explained, in discussing the patents at issue in that appeal, that each claim "expressly recites an additional efficacy limitation ***that further restricts the method of administering the composition twice daily***: (1) 'without loss of efficacy' in claim 4 of the '149 patent … ; (2) 'a therapeutically effective amount' in claim 1 of the '976 patent … ; and (3) 'reduc[ing] the incidence of one or more adverse events' in claim 1 of the '425 patent." *Allergan Sales, LLC v. Sandoz, Inc.*, 717 F. App'x 991, 994 (Fed. Cir. 2017).[1] The Court further concluded that "[t]he efficacy limitations are also ***not inherent*** in the administration of the ophthalmic composition, a finding adequately supported by the record." *Id*.

The same efficacy and adverse event requirements that were in the claims addressed by the Federal Circuit are also in the "wherein" clauses here. (Dkt. 57 at 12.) Just as with the prior claims, the "wherein" requirements here are more than a statement of inherent result. They add a material limitation—only formulations achieving the claimed results are covered. Sandoz's contrary arguments directly conflict with the Federal Circuit, and this Court should reject them.

Sandoz's arguments about the "wherein" clauses are also inconsistent with the case law

[1] All emphasis in quotations is added unless otherwise noted.

Allergan cited in its opening and responsive claim construction briefs—case law Sandoz was aware of well before it responded to Allergan's preliminary injunction motion but chose not to address here. That is because Sandoz has no answer to the law providing that, in determining whether a "wherein" clause is limiting, "the ***key question*** is whether or not the clause states a condition material to patentability." *Shire LLC v. Amneal Pharms., LLC*, Nos. 11-CV-3781 (SRC), *et al.*, 2013 U.S. Dist. LEXIS 111773, at *58 (citing *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329 (Fed. Cir. 2005)). If the "wherein" clause is material to patentability, it "cannot be ignored in order to change the substance of the invention." *Hoffer*, 405 F.3d at 1329.

Under this case law, contrary to what Sandoz would have this Court believe, it is common for "wherein" or similar types of clauses relating to "results" in clinical method claims to be limiting because they are material to patentability. For example, the Federal Circuit applied this principle in *Griffin v. Bertina*, 285 F.3d 1029, 1033-34 (Fed. Cir. 2002), finding that the phrase "wherein the presence of said point mutation in said test nucleic acid indicates an increased risk for thrombosis or a genetic defect causing thrombosis" in a claim to a diagnostic method was limiting because that clinical correlation "indicate[d] the purpose of the method" and was "material to the patentability of the count." Similarly, in *AstraZeneca AB v. Reddy's Labs., Ltd.*, No. 05-5553 (JAP), 2010 U.S. Dist. LEXIS 48844, at *31, 53-54 (D.N.J. May 17, 2010), a court in this District applied the same rule in a case that involved claims to methods of treating gastric acid related diseases. The court found both a "so as to" clause related to plasma levels and a "wherein" clause related to improved clinical effects to be limiting, reasoning that they "provide[d] the necessary purpose to the steps" and claimed the "***unexpected and improved effects*** of administration of the claimed compound on individuals." *Id.* at *34-35. And in *Javelin Pharmaceuticals, Inc. v. Mylan Labs. Ltd.*, No. 16-224-LPS, 2017 U.S. Dist. LEXIS 166762, *8

(D. Del. Oct. 10, 2017), the district court in Delaware applied the same rule when it construed "wherein" clauses directed to drug efficacy to be limiting because, "although the 'wherein' clause ***recites a result*** of the claimed method, it is also material to patentability."

Here, the efficacy and adverse event requirements in the "wherein" clauses are similarly limiting because they are "material to patentability" of the claims and provide the "necessary purpose" to the steps, reciting the "unexpected and improved effect" of the claimed methods. *AstraZeneca*, 2010 U.S. Dist. LEXIS 48844, at *34-35. Sandoz's repeated refrain that the clauses cannot be limiting because they relate to "results" is contrary to the law.

**1. Sandoz's Arguments that the "Wherein" Clauses Are Not Limiting Conflict with the File Histories of the Patents-in-Suit**

The file histories of the patents-in-suit, which Sandoz also ignores, further demonstrate the materiality of the "wherein" clauses to the patentability of the claims—the Examiner who granted the three patents-in-suit relied expressly on the content of "wherein" clauses to find that each of the asserted claims was patentable over the prior art. The Examiner initially rejected the pending claims of the '453 patent, which contained the same "wherein" clauses with the efficacy and adverse event limitations as the asserted claims, as obvious because she found that those clauses were "the intended result of an otherwise obvious process step of the claims," as Sandoz wrongly argues. But the Examiner changed her mind after reviewing the district court and Federal Circuit opinions, which Allergan provided in an office action response. (Dkt. 57, Ex. Z at AGN_COM00765424-427, AGN_COM00765498-517.) After reviewing those opinions, the Examiner allowed the claims and ***relied on*** the limitations in the "wherein" clauses, explaining her reasoning in her Statement of Reasons for Allowance as follows:

> [T]he cited reference(s) alone or in combination fail(s) to teach the reduction of adverse events as compared to the administration of 0.2% w/v brimonidine tartrate monotherapy three times a day ***as claimed***. … One of ordinary skill in the art would not have expected that the combination of timolol with brimonidine in a

> single composition would reduce the adverse events experienced by a patient taking 0.2% w/v brimonidine tartrate monotherapy. Applicant also showed that the twice daily administration of the claimed composition eliminates the "afternoon trough" (a loss of efficacy eight to nine hours post administration) of twice daily administration of brimonidine monotherapy, which was recognized as unexpected by the US district court in the infringement suits of the parent cases. See "Findings of Fact and Conclusions of Law and the Opinion and Final Judgment" of US district court made on December 30, 2016 (cited in the IDS filed on 2/23/2017) and Applicants' arguments filed on 4/28/2017 for details. Thus, the instant method is novel and non-obvious over the prior art.

(*Id.* at AGN_COM00765792-93; *see also id.*, Ex. BB at AGN_COM00766150-51 and *id.*, Ex. CC at AGN_COM00766496 (Notices of Allowance for '801 and '802 patents).)

Because Allergan and the Examiner both treated the "wherein" clauses as limiting during prosecution, and they were key to the allowance of the claims, those clauses are material to patentability and are limiting. The facts in this case are similar to those of *Javelin Pharmaceuticals*, where the court found the clause "wherein the method achieves at least about 82% of maximum observable total pain relief" in claims to a method of treatment with diclofenac to be limiting because it was material to patentability based on the arguments in the file history. 2017 U.S. Dist. LEXIS 166762, at *7-10 ("[T]he applicants relied on the formulation's efficacy in responding to the examiner's rejection for obviousness[,]" and those arguments "demonstrate that efficacy—i.e., what is described by the disputed wherein clause—was used to define the claimed invention and distinguish it from the prior art.").

**2. Sandoz's Arguments that the "Wherein" Clauses Are Not Limiting Conflict with Its Prior Positions**

Sandoz's own positions on "wherein" clauses in the previous litigations further demonstrate the weakness of Sandoz's position here. Sandoz repeatedly states that the parties never litigated the issue of whether the wherein clauses were limiting in the claims asserted in the prior cases. That is simply inaccurate. As discussed above, the Federal Circuit expressly found that similarly structured limitations in related patents "further restrict[] the method of

administering the composition." *Allergan Sales*, 717 F. App'x at 994. And there can be no dispute that the parties litigated the constructions of terms appearing in those wherein clauses—indeed, the parties proposed different constructions for those terms—and then litigated those clauses as limitations on the claims. For example, in the parties' first litigation over Sandoz's full-labeled product, Allergan and Sandoz proposed constructions for terms appearing in the phrase "***wherein*** the method is as effective as administration of 0.5% timolol twice a day and 0.2% brimonidine three times a day to said eye, ***wherein*** the two compounds are administered in separate compositions." (Dkt. 57, Ex. P at 9:14-10:4.) Sandoz ultimately prevailed on its constructions and obtained summary judgment of non-infringement of claims 1-3 of the '149 patent based on limitations in the "wherein" clause of those claims. (*Id.*, Ex. R; *id.*, Ex. S at 7.)

In the second litigation, Sandoz again proposed a construction of the term "as compared to brimonidine in the absence of timolol" in the phrase "***wherein*** the method results in a lower incidence of one or more adverse events, as compared to brimonidine in the absence of timolol" in the '890 patent. (*Id.*, Ex. EE; *id.*, Ex. U at 10-13, 21-24.) In asserting a failed non-infringement argument, Sandoz relied on the reduced adverse event language that appeared only in the "wherein" clause, arguing that "[n]either Sandoz nor Alcon is seeking FDA approval for a method that reduces adverse event incidence relative to brimonidine monotherapy, ***an element that is required by each of the asserted claims***." (*Id.*, Ex. V, ¶¶ 52-57.)

Sandoz's prior arguments strongly counsel that its position here is one of convenience, not legal merit. Even putting the prior arguments aside, the law squarely rejects Sandoz's position, and its failure to address those cases is telling. The "wherein" clauses are limiting.

### C. Sandoz's Exclusive Reliance on Attorney Argument Does Not Rebut Allergan's Likelihood of Success on the Merits

Beyond its arguments on the "wherein" clause, Sandoz offers the Court a hodge-podge of

assertions about Allergan's patents that are not supported by any expert declarations.[2] This also counsels strongly in favor of granting Allergan's motion. Courts often find that a defendant fails to rebut a patent owner's likelihood of success where the defendant fails to put forward any expert evidence to support its arguments. *See, e.g.*, *CryoLife, Inc. v. C.R. Bard, Inc.*, No. 14-559-SLR, 2015 WL 1093543, at *3 (D. Del. Mar. 10, 2015) (finding likelihood of success on validity when defendant's arguments were not supported by expert testimony, but only "a table of invalidity contentions and the barest of attorney argument"); *Fred Hutchinson Cancer Research Ctr. v. BioPet Vet Lab, Inc.*, 768 F. Supp. 2d 872, 880–81 (E.D. Va. 2011) ("In light of the fact that Defendants failed to present any credible or persuasive testimony by a person skilled in the art to support its allegations of invalidity and the fact that the Koskinen article is not prior art under 35 U.S.C. § 102, this Court finds that Defendants have failed to raise a 'substantial question of invalidity.'"); *Symbol Techs., Inc. v. Janam Techs. LLC*, 729 F. Supp. 2d 646, 661 (D. Del. 2010) (finding likelihood of success on infringement when defendant's "sole contention on non-infringement came at oral argument"). This Court should respectfully find the same.

### D. The Balance of Harms Strongly Favors Granting a Preliminary Injunction

#### 1. Sandoz's "Unclean Hands" Argument Is Improper and Meritless

Sandoz does not attempt to use its meritless inequitable conduct defense to support a likelihood of success on the merits, but devotes about a dozen pages to the allegations behind that defense in its "background" section. It then repackages those allegations to argue "unclean hands"

[2] For example, Sandoz offers attorney argument about the formulation limitations in some of the dependent claims. This argument contradicts findings in the first litigation over Sandoz's full label, where the Federal Circuit found "no error in the district court's findings that Allergan's formulators faced difficulties in developing Combigan®," but noted that the claims at issue there "were not drawn to the Combigan® formulation with any specificity given that Combigan® contains many elements in addition to those embodied in the claims." *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1292 (Fed. Cir. 2013).

in its argument about the balance of equities. This is improper under the law.

Because Sandoz bases its vague "unclean hands" claim on the very same facts about the prosecution of patents over a decade ago on which its inequitable conduct claims rest, it must meet the stringent requirements for inequitable conduct and cannot shortcut them by attaching a different label to the allegations. As the Federal Circuit explained in *Regents of the University of California v. Eli Lilly Co.*, 119 F.3d 1559, 1571 (Fed. Cir. 1997), it will not "afford equitable relief" in the "guise" of unclean hands "in the absence of proof of materiality" because "materiality is a necessary ingredient of any inequitable conduct." Sandoz cannot avoid the requirements for inequitable conduct by calling it something different and arguing it as a matter of equity. *See Fresenius Kabi USA, LLC v. Fera Pharm., LLC*, No. 15-CV-3654 (KM)(MAH), 2016 U.S. Dist. LEXIS 128126, at *37-38 (D.N.J. Sept. 20, 2016 ) (finding that defendant's unclean hands argument was indistinguishable from its inequitable conduct contentions, which "have no more likelihood of success under the rubric of unclean hands"); *Chamberlain Grp., Inc. v. Techtronic Indus. Co.*, No. 16-C-6097, 2017 WL 1101092, at *17 (N.D. Ill. Mar. 22, 2017) (denying leave to amend "where an accused infringer's unclean hands defense is based on alleged acts of inequitable conduct, it rises and falls based on those allegations").

For the reasons described in Allergan's motion to dismiss (Dkt. 112-1), Sandoz cannot meet the materiality and intent requirements to show inequitable conduct as a matter of law. But even beyond this, Sandoz's arguments in its opposition brief, based on materials of record from the prior cases, are not supported by the facts. For example, the claim language of the '802 patent requires a comparison between the adverse events experienced by patients treated with Combigan® twice daily and brimonidine three times daily. (Dkt. 116, Ex. 3 at 9:12-32.) When that comparison is made, contrary to Sandoz's arguments, the 12T and 13T studies have similar

results. For the adverse event of somnolence, which Sandoz presses in its brief, the Combigan® group experienced less somnolence than the brimonidine group in both studies at each point:

| Somnolence | Comb | Brim | Timolol |
|---|---|---|---|
| 12T 3-month data | 2.1% | 3.8% | 1.0% |
| 12T 12-month data | 2.1% | 4.3% | 1.0% |
| 13T 3-month data | 1.0% | 3.6% | 0.0% |
| 13T 12-month data | 1.0% | 3.6% | 0.0% |

(Noecker Decl., Ex. 4 (Table 23.1), Ex. 2 (Table 23.1), Ex. 11 (Table 20.1), Ex. 1 (Table 20.1).)

Allergan's other clinical studies show the same. While Sandoz criticizes the four-week duration of Allergan's 19T study, the study found that the rate of nervous system adverse events, which includes somnolence, was statistically significantly lower in the Combigan® group than in the brimonidine group. (Dkt. 116, Ex. 40 at 8.) The data are thus no different than those from the longer-duration studies conducted by Allergan in relation to the claimed reduction in adverse events. (Noecker Decl., ¶¶ 15-23.) Sandoz's arguments that the 507T study is to the contrary and was improperly withheld (Dkt. 115 at 11) is just wrong; Sandoz admits the study was disclosed (*id.* at 12), and Sandoz ignores that its arguments about the scientific import of 507T were rejected on the merits after a full trial. (Dkt. 86-10, Ex. A, ¶¶ 155-60.) And while FDA may not have approved Combigan® based on Allergan's 23T study, an exploratory analysis of the data in 23T, done at FDA's suggestion, revealed "that a statistically significant difference in sleepiness responders could have been demonstrated if there had been older patients enrolled in the study." (Noecker Decl., ¶¶ 22; *id.*, Ex. 5 at 61, 64.) FDA therefore "encouraged [Allergan] to conduct a repeat study in older patients to confirm the findings of the exploratory analysis." (*Id.*, Ex. 5 at 61.) Allergan did just that in the 24T study, which confirmed to FDA's satisfaction Combigan® offered an advantage in reduced sleepiness. (*Id.* at 40.)

Far from being "conflicting" or "unfavorable," the data behind Combigan®'s patented

improved safety profile, and sleepiness in particular, *is the reason the drug was approved*—"Allergan has demonstrated that the fixed combination, alternative dosing regimen would provide a useful product because the safety profile of the proposed combination product is better than that of the individual agents taken as currently permitted in the approved labeling." (Noecker Decl., Ex. 5 at 12.) And contrary to Sandoz's allegations, FDA's Medical Review was cited to the Patent Office and considered in granting the patents-in-suit. (Walsh Decl. Ex. O at AGN_COM00681962; *id.*, Ex. P at AGN_COM00682594; *id.*, Ex. Q at AGN_COM00761650; *id.*, Ex. R at AGN_COM00765220; *id.*, Ex. S at AGN_COM00765925; *id.*, Ex. T at AGN_COM00766301.) Because Sandoz cannot meet the inequitable conduct standard, its unclean hands allegations should also be dismissed.

**2. Allergan's Showing of Irreparable Harm is Unrebutted**

Sandoz does not dispute any of the facts demonstrating Allergan's irreparable harm in the event of a generic launch. And neither of the cases Sandoz cites support its argument that Allergan's loss of market share, loss of revenue, and price erosion after generic entry can be compensated by money damages.[3] Here, Allergan has offered unrebutted evidence of irreparable harm (Dkt. 86-5; Dkt. 86-8), and the patents-in-suit cover Allergan's Combigan® product. In those circumstances, the Federal Circuit has repeatedly found that economic harms caused by generic entry are irreparable and warrant temporary injunctive relief. *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 872-73 (Fed. Cir. 2017); *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1361-62 (Fed. Cir. 2008).

[3] *See Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1347-48 (Fed. Cir. 2006) (irreparable harm prong did not favor either party based on lack of evidence); *Graceway Pharms., LLC v. Perrigo Co.*, 697 F. Supp. 2d 600, 608 (D.N.J. 2010) (plaintiff's delay in bringing suit and fact that asserted patent did not cover the patentee's product weighed against irreparable injury).

Likewise, Allergan's loss of employees, R&D revenue, managed care position, and goodwill would be the result of Sandoz's generic launch (Dkt. 86-5 ¶¶ 26-34; Dkt. 86-8 ¶¶ 13-18), not "the direct results of Allergan's own choices"[4] as Sandoz argues (Dkt. 115 at 32 n.11). These harms are irreparable. *See, e.g.*, *AstraZeneca LP v. Apotex, Inc.*, 623 F. Supp. 2d 579, 612 (D.N.J. 2009); *Fresenius Kabi*, 2016 U.S. Dist. LEXIS 128126, at *41-42.

Dated: June 5, 2018

Respectfully submitted,

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[4] The cases Sandoz cites for this point have nothing to do with irreparable harm in the context of a generic drug launch. *See Caplan v. Fellheimer Eichen Braverman & Kaskey*, 68 F.3d 828, 839 (3d Cir. 1995) (finding in a sex discrimination lawsuit that harm was of defendants' own making where defendants were displeased with terms on which their insurance carrier settled, but they had authorized the carrier to settle the case); *San Francisco Real Estate v. Real Estate Invest. Trust of Am.*, 692 F.2d 814, 818 (1st Cir. 1982) (finding in a securities case that shareholders had time to tender shares under the deadlines, and any failure to do so was self-inflicted harm).

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